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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/986,775	11/09/2001	Gholam A. Peyman	42571	5633

1609 7590 06/17/2003

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 WASHINGTON,, DC 20036

EXAMINER

MILLER, CHERYL L

ART UNIT	PAPER NUMBER
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3738

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DATE MAILED: 06/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.		Applicant(s)	
	09/986,775		PEYMAN, GHOLAM A.	
	Examiner		Art Unit	
	Cheryl Miller		3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspond nce address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) 1-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Election/Restrictions***

Applicant's election with traverse of Group II, claims 27-32 in Paper No. 8 is acknowledged. The traversal is on the ground(s) that because the allegedly separate inventions are closely related, there is not a serious burden on the Examiner. This is not found persuasive because Group I. is directed toward a surgical method and Group II. is directed toward an implant. The surgical method requires marking the cornea surface, separating the cornea forming two surfaces, and placement of an inlay in between the corneal layers, whereas the inlay implant may be implanted and aligned by a different method, such as placement on the outer surface of the cornea, such as contact lens do, or injection of the inlay, or by lasering a hole or channel into the cornea and insertion of the inlay into the hole or channel. The examiner refers applicant to the election restriction requirement in paper no.7. The two groups are classified in different areas, the inlay implant of Group II classified in 623/5.11, and the inlay alignment method being classified in 623/906, and because it is a surgical method, the class 606/4 and 606/5 would also need to be searched, creating a burden on the examiner, because of the different status in the art.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 36-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 36 recites the limitation "a mark on the center of the inlay" and "axes extending from the center of the inlay in a direction toward the periphery of the inlay" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim. Claim 36 depends upon claim 28, which requires the markings to be on the sheet, not the inlay as claimed in 36. It is suggested to change "a mark on the center of the inlay" to recite --a mark on the center of the sheet-- and --axes extending from the center of the sheet in a direction toward the periphery of the sheet--.

Claim 37 recites the limitation "said markings" in line 3. There is insufficient antecedent basis for this limitation in the claim. Earlier in the claim the applicant defines "a removable marking". It is suggested to change "said markings" to recite --said marking--. Claims 38-44 depend upon claim 37 and inherit all problems associated with the claim.

Claim 42 recites the limitation "said corresponding marking on the surface of the cornea" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim. Applicant has not positively claimed markings on the cornea. Also, it is noted that it is improper to positively claim markings on the cornea, since this would be positively claiming a portion of the body, which is non-statutory subject matter (see 35 U.S.C. 101).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 28, 30-33, 37-38, and 41-43 are rejected under 35 U.S.C. 102(e) as being anticipated by Nigam (Pub. No. US 2002/0029981 A1). Referring to claims 28, 37, and 38, Nigam discloses an inlay (40, 92) comprising a first surface, second surface, and a removable sheet of material (45) overlaying the second surface (figs. 14b-14d), the sheet having markings (22, 23, 24, 29) thereon for positioning (0042, 0043, 0049) or removable markings (94) on the inlay (figs. 18-20; 0070, 0071, inherently the markings are removable since they are engraved, or printed with ink, they may be removed by sanding, resurfacing, or the ink may dissolve over time). Referring to claims 30 and 41, Nigam discloses an asymmetric inlay (figs. 18-20; asymmetric 0070, 0071; astigmatism 0002, 0004). Referring to claims 31 and 42, Nigam discloses a transparent inlay (0002, 0005). Referring to claim 32, Nigam discloses a pliable conforming sheet (0010, 0055). Referring to claims 33 and 43, Nigam discloses a pliable inlay (40) for positioning between surfaces of the cornea (37, 39; fig. 14a-14e).

Claims 37 and 41-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Nigam (USPN 6,102,946, cited by applicant in IDS). Referring to claim 37, Nigam discloses an inlay (74) comprising a first surface, second surface, and a removable marking (col. 2, lines 50-56;

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col.6, lines 35-44; col.8, lines 31-34, 45-46) on a surface indicating at least one axis (x,y, fig.11-16). Since the markings may be in ink, or protrusions, it is inherent that the markings may be removed, by sanding, resurfacing, or dissolution over time. Referring to claims 41-43, Nigam discloses an asymmetric (col.6, lines 12-30), transparent (col.2, lines 65-67; col.6, lines 31-32), and pliable inlay for positioning between two corneal surfaces (figs.7a-10, 21a-21b). Referring to claim 44, Nigam discloses a center mark and at least two radial axes (x, y) extending from the center to the periphery (figs.11-14, 20a; col.2, lines 46-56).

Claims 28, 32-33, 37-38, and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Choyce (USPN 4,655,774, cited by applicant in IDS). Referring to claims 28, 37, and 38 Choyce discloses an inlay (10) comprising a first surface, second surface, and a removable sheet of material (instrument, fig.5, col.2, lines 63-68) overlaying the second surface, the sheet having markings (markings being the inner boundaries or edges of the instrument) thereon for positioning or removable markings on the inlay. Referring to claim 32, Choyce discloses a pliable conforming sheet (fig.5, col.2, lines 63-67). Referring to claims 33 and 43, Choyce discloses a pliable inlay for positioning between surfaces of the cornea (fig.3a-4).

Claims 37 and 41-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Reynolds (USPN 4,452,235, cited by applicant in IDS). Referring to claim 37, Reynolds discloses an inlay (47) comprising a first and second surface, and a removable marking (81, fig.11, removable marking is a target image and is inherently removable) on one surface indicating one axis (col.7, line 60-col.8, line 7). Referring to claims 41-43, Reynolds discloses an inlay that is asymmetric (col.6, lines 45-47), transparent (col.6, lines 40-42), and pliable to positioned between two surfaces of the cornea (fig.4). Referring to claim 44, Reynolds discloses

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an inlay (47) having a center mark and at least two radial axes extending from the center to the periphery of the inlay (81, fig.11; col.7, lines 3-6).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 29, 34-36, 39-40 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nigam (Pub. No. US 2002/0029981 A1). Nigam discloses markings on an inlay (40) or removable sheet (45) for the same purpose of aligning and positioning the inlay (0042, 0043, 0049, 0054, 0070, 0071), the markings having a center mark (23) and outer marks (22, 24, 29), however does not disclose the markings being radial axes extending from the center to the periphery. It would have been obvious to one of ordinary skill in the art at the time the invention was made to mark the sheet with radial axes instead of radial circles or holes, since both serve the same purpose of alignment and angular positioning, as such would merely constitute substitution of functionally equivalent markings.

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Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (703) 305-2812. The examiner can normally be reached on Monday through Friday from 7:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



Cheryl Miller

June 11, 2003



BRUCE SNOW
PRIMARY EXAMINER